

Art Unit: 1654

### EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lisa Hillman on July 19, 2011.

The application has been amended as follows:

Please amend **claim 6** as follows:

--"The method of claim 1 further comprising:

(e) expressing and isolating a polypeptide from the isolated polynucleotide of claim 1;

(f) producing antibodies to the polypeptide; and

(g) demonstrating that the antibodies are reactive with biological samples from disease sites from a host naturally infected with the microbe or pathogen, but not reactive with cells or cellular extracts of the microbe or pathogen that have been grown *in vitro*; whereby the isolated polynucleotide is confirmed as being expressed only *in vivo*."--

Please amend **claim 11** as follows:

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--“A method of comparing polynucleotides of a microbe or pathogen that are expressed only *in vivo* and at different stages of infection of the microbe or pathogen comprising the steps of:

(a) obtaining a first antibody sample from one or more hosts naturally infected with the microbe or pathogen, wherein each host is in about the same stage of the infection;

(b) adsorbing the first antibody sample with cells or cellular extracts of the microbe or pathogen that have been grown *in vitro*;

(c) obtaining a second antibody sample from one or more hosts naturally infected with the microbe or pathogen, wherein each host is in about the same stage of the infection, wherein the stage of the infection is different from the stage of infection in step (a);

(d) adsorbing a the second antibody sample with cells or cellular extracts of the microbe or pathogen that have been grown *in vitro*;

(e) isolating unadsorbed antibodies from the first antibody sample and from the second antibody sample;

(f) probing a first expression library of clones of the microbe or pathogen with the unadsorbed antibodies from the first antibody sample and isolating clones from the first expression library to which the unadsorbed antibodies bind, and probing a second expression library of clones of the microbe or pathogen with the unadsorbed antibodies from the second antibody sample and isolating clones from the second expression library to which the unadsorbed antibodies bind, wherein polynucleotides of the microbe or pathogen that are expressed only *in vivo* are isolated for the first and second antibody sample; and

(g) comparing the polynucleotides of the microbe or pathogen that are expressed only *in vivo* and at different stages of infection of the microbe or pathogen.”--

Please amend **claim 13** as follows:

--“A method of comparing polynucleotides of a microbe or pathogen that are expressed only *in vivo*, wherein the microbe or pathogen has naturally infected its host by different routes of infection comprising the steps of:

(a) obtaining a first antibody sample from one or more hosts naturally infected with the microbe or pathogen, wherein each host has been naturally infected by about the same route of infection;

(b) adsorbing the first antibody sample with cells or cellular extracts of the microbe or pathogen that have been grown *in vitro*;

(c) obtaining a second antibody sample from one or more hosts infected with the microbe or pathogen, wherein each host has been infected by about the same route of infection, wherein the route of infection is different from the route of infection in step (a);

(d) adsorbing the second antibody sample with cells or cellular extracts of the microbe or pathogen that have been grown *in vitro*;

(e) isolating unadsorbed antibodies from the first antibody sample and from the second antibody sample;

(f) probing a first expression library of clones of the microbe or pathogen with the unadsorbed antibodies from the first antibody sample and isolating clones from the first expression library to which the unadsorbed antibodies bind, and probing a second expression

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library of clones of the microbe or pathogen with the unadsorbed antibodies from the second antibody sample and isolating clones from the second expression library to which the unadsorbed antibodies bind, wherein polynucleotides of the microbe or pathogen that are expressed *in vivo* are isolated for the first and second antibody sample; and

(g) comparing the polynucleotides of the microbe or pathogen that are expressed only *in vivo* by different routes of infection of the microbe or pathogen.”--

Please amend **claim 15** as follows:

--“A method of confirming an animal model of infection as a valid model comprising the steps of:

(a) obtaining a first antibody sample from one or more first animal model hosts naturally infected with a microbe or pathogen;

(b) adsorbing the first antibody sample with cells or cellular extracts of the microbe or pathogen that have been grown *in vitro*;

(c) obtaining a second antibody sample from one or more second hosts naturally infected with the microbe or pathogen, wherein the second host is a different species of animal than the first animal model host;

(d) adsorbing a the second antibody sample with cells or cellular extracts of the microbe or pathogen that have been grown *in vitro*;

(e) isolating unadsorbed antibodies from the first antibody sample and from the second antibody sample;

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(f) probing a first expression library of clones of the microbe or pathogen with the unadsorbed antibodies from the first antibody sample and isolating clones from the first expression library to which the unadsorbed antibodies bind, and probing a second expression library of clones of the microbe or pathogen with the unadsorbed antibodies from the second antibody sample and isolating clones from the second expression library to which the unadsorbed antibodies bind, wherein polynucleotides of the microbe or pathogen that are expressed only *in vivo* are isolated for the first and second antibody sample; and

(g) comparing the polynucleotides of the microbe or pathogen that are expressed only *in vivo* in the first animal model host and the second host; wherein if the polynucleotides expressed only *in vivo* in the first animal model and in the second host are the same or similar, then the first animal model is confirmed as a valid model.”--

Please note: the restriction requirement of record has been withdrawn.

#### ***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Amber D. Steele/

Primary Examiner, Art Unit 1654